

HITRD RFI Responses, March 15, 2019

ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

DISCLAIMER: The [RFI public responses](#) received and posted do not represent the views and/or opinions of the U.S. Government, NSTC Subcommittee on Networking and Information Technology Research and Development (NITRD), NITRD National Coordination Office, and/or any other Federal agencies and/or government entities. We bear no responsibility for the accuracy, legality or content of all external links included in this document.

MP190197

March 15, 2019



**Response of The MITRE Corporation to the NSTC/NITRD Request for Information
on Action on Interoperability of Medical Devices, Data, and Platforms to
Enhance Patient Care**

For additional information about this response, please contact:

Duane Blackburn, S&T Policy Analyst

The MITRE Corporation

[Redacted]

[Redacted]

[Redacted]

[Redacted]

This page intentionally left blank.

Introduction

The MITRE Corporation is a not-for-profit company that works across government to tackle difficult problems that challenge the safety, stability, security, and well-being of our nation through its operation of multiple federally funded research and development centers (FFRDCs), as well as public-private partnerships. Working across federal, state, and local governments, as well as industry and academia, gives MITRE a unique vantage point. MITRE works in the public interest to discover new possibilities, create unexpected opportunities, and lead by pioneering together for public good to bring innovative ideas into existence in areas such as artificial intelligence, intuitive data science, quantum information science, health informatics, policy and economic expertise, trustworthy autonomy, cyber threat sharing, and cyber resilience.

MITRE has significant experience working across the operating divisions of the Department of Health and Human Services (HHS), and also in helping to create numerous public-private partnerships that implement innovative ideas to solve our nation's toughest health problems. We welcome the opportunity to respond to this National Science and Technology Council (NSTC) Request for Information.

Interoperability of medical devices, data and platforms is a dynamic and far-reaching area, spanning numerous complex issues such as standards, communications platforms, monitoring models, control systems. MITRE's response to this RFI focuses on a fundamental matter, for devices to securely communicate¹ over the internet with a common messaging protocol, which must be established before other issues can properly be addressed.

Please let us know if you have any questions on this submission, or if we can help you succeed in any other way.

RFI Question #4²: Is the federal vision for a medical device, data, and platform interoperability end state outlined in this RFI viable? Please explain why you have reached the conclusion that you have.

MITRE has reviewed the draft federal vision included within the RFI and believes that it is indeed viable. The concepts are technically feasible, with some of the described functionality partially in practice, e.g. the Integrating Healthcare Enterprise Patient Care Device interoperability domain framework³. Although this framework and the profiles that fall under it allow for medical device, data, and platform interoperability, they often use dated messaging protocols that were created before internet-based messaging protocols were mainstream⁴. Examples of how these messaging profiles are currently used include:

¹ Note as well that most medical devices and systems communicate via a gateway server, rather than via direct connection between two devices.

² MITRE felt this question was foundational to the remainder of our response, thus we led with it.

³ https://www.ihe.net/resources/technical_frameworks/#pcd

⁴ For further detail, see <https://www.hl7.org/fhir/comparison-v2.html>

- The Large Volume Pump (LVP) or Infusion Pump’s use of the Alert Communication Management (ACM) profile⁵ for alert and alarm management. This profile is currently used to communicate events such as a low battery alert to a backend gateway or central server. It is also used to communicate clinical based alarms, such as completion of drug delivery.⁶
- The Device Equipment Communication (DEC) profile, which is used to communicate details about a device’s status, such as which patient is currently using a specific device.
- The MEMLS (Medical Equipment Location Services) and MEM (Medical Equipment Management) profile, which are used for sharing a device’s location.
- The Infusion Pump Event Communication (IPEC) and Point-of-care Infusion Verification (PIV) profiles. IPEC is used for monitoring a formulary being delivered real-time, and PIV is used for “Five Rights”⁷ validation. Together they allow for some of the components to a Drug Error Reduction System (DERS).

For the most part, these examples use an older HL7 v2 protocol and do not work well with internet-based protocols. Newer messaging protocols—such as Fast Healthcare Interoperability Resources (FHIR), which uses representational state transfer (REST)—are made up of the Hyper Text Transfer Protocol Secure (HTTPS) and JavaScript Object Notation (JSON), technologies designed to leverage interoperability over internet-based medical devices and related medical systems.

RFI Question #1: What is your vision for addressing interoperability issues between medical devices, data, and platforms? How would this plan to create interoperable systems address your key use cases and pain points?

MITRE has limited its response to this RFI on the fundamental issue of enabling devices to securely communicate with a common messaging protocol. A key component of this plan includes the establishment of/enablement of a common messaging protocol that can transition medical devices to a point where they leverage the HL7 FHIR protocol as their baseline⁸. Device and application profiles can then be developed to enable constraints on resources and data types, as well as terminology binding statements and extension definitions. The development of Implementation Guides and reference implementations would be critical to the broader dissemination and adoption of this approach.

⁵ An HL7 message *profile* is an unambiguous specification of one or more standard HL7 messages that have been analyzed for a particular use case.

⁶ An added advantage of the RFI’s future vision will be to reduce “alarm fatigue,” which occurs when a human becomes overburdened with alarms within a clinical environment. In the future state, these alarms would be sent to a central server that could organize and display information on a single dashboard that is optimized to support the patient’s individual care needs.

⁷ The Five Rights of Medication Administration: the right patient, the right drug, the right dose, the right route, and the right time.

⁸ Some interoperability projects may simply add an HL7 FHIR interface on top of legacy HL7 v2 interfaces. While not ideal, it is still a step in the right direction as it improves security and allows users to phase out HL7 v2 on their own timeline.

Strategic modernization is required to better enable interoperability between medical devices, data, and platforms. For example, although frameworks like the Patient Care Device framework are currently used to support healthcare interoperability, they use the older version of HL7 messaging, HL7 v2. This version is not secure and robust enough to meet the government's vision. It currently uses the Minimal Lower Layer Protocol, which is essentially the TCP/IP protocol with additional header and trailer characters to identify the beginning and the end of the message. *Security is not included*⁹. The newer HL7 FHIR protocol enables, but does not require, the use of HTTPS, which adds an initial layer of security.

RFI Question # 2: Who are the relevant parties and their contributions to your interoperability solution?

HL7's "Da Vinci" project¹⁰ is working to modernize messaging standards using FHIR, implementation guides, and reference implementations. A similar approach can be taken that is focused on medical devices and related medical systems by bringing together medical device vendors, EHR providers, and health device integrators.

RFI Question #3: What are the challenges and impediments to making interoperability happen? How might these issues be addressed and by whom?

Highly aligned with the state-of-industry goals, MITRE's vision to move medical device interoperability forward is based on the critical activity of ensuring devices can securely communicate using a common messaging protocol. The realization of this vision will be challenging, and additional interoperability challenges will be encountered, but advancements can be built upon this secure foundation.

These additional challenges will vary depending on the specific entities that must collaborate. For example, enabling interoperability between a public health center's existing EHR and new data aggregation software will likely require significant human effort to enable proper data exchanges. That is

⁹ For example, HL7 v2 is subject to man-in-the-middle attacks. See https://acsweb.ucsd.edu/~mbland/pestilential_protocol.pdf

¹⁰ <http://www.hl7.org/about/davinci/index.cfm>

certainly an achievable task but one that requires time and effort. (In most cases, it takes less time than establishing the legal agreements, which must also be developed to allow it to happen.)

Another challenge or impediment is the creation of Implementation Guides (IG). For example, in the provider-payer interoperability industry, IGs are used to connect EHRs and billing management systems. Once created, IGs can greatly reduce the time and effort of implementing individual interoperability activities. Creating the IGs is a time-consuming process, however, as they must be developed, tested to ensure they will work properly, and then formalized within a respected standards body. Efforts to fast-track this development and approval process should be investigated.

Additional Information

MITRE has relationships with organizations working to improve interoperability within the healthcare system. Three prominent activities are listed here so that NITRD can communicate with the respective organizations as they move forward:

- [Personal Connected Health Alliance \(PCHAlliance\)](https://www.pchalliance.org/continua-design-guidelines)¹¹. PCHAlliance publishes and promotes the Continua Design Guidelines, the only open implementation framework for authentic, end-to-end interoperability of personal connected health devices and systems. The current version is built on Continua Design Guidelines HL7 (Health Level Seven) Fast Healthcare Interoperability Resources (FHIR).
- [Open-Source Integrated Clinical Environment \(OpenICE\)](https://www.openice.info/docs/1_overview.html)¹². OpenICE is a prototype clinical ecosystem connecting medical devices and clinical applications. It provides a framework for the integration of devices and applications into the broader Medical Internet of Things.¹³
- The health IT and broader stakeholder community is actively working to integrate medical devices, EHRs, and the broader data generated in the healthcare industry. Many stakeholders (e.g., IHE International Patient Care Device¹⁴, Devices on FHIR¹⁵, and IEEE 11073 Point of Care Device standards¹⁶) work in conjunction with HL7 in support of the new HL7 FHIR protocol.

¹¹ <https://www.pchalliance.org/continua-design-guidelines>

¹² https://www.openice.info/docs/1_overview.html

¹³ Although Openice features are good, it currently requires connection via a device serial port. Newer and more secure devices are often wireless however, thus necessitating future updates.

¹⁴ https://www.ihe.net/ihe_domains/patient_care_devices/

¹⁵ http://wiki.hl7.org/index.php?title=Devices_on_FHIR

¹⁶ <https://standards.ieee.org/standard/11073-10201-2018.html>